

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of the Claims:

Claim 1 (currently amended): A method for the treatment, prophylaxis, or reduction of the risk of developing a menopause disorder in a human female mammalian subject in need thereof, comprising a combination therapy of:

(a) orally administering a first pharmaceutical composition comprising about 0.2 mg to about 50.0 mg of methyltestosterone; and

(b) percutaneously administering to a selected area of skin, about 5 g to about 10 g per day of a second pharmaceutical composition comprising: about 0.1 mg to about 10.0 mg of estradiol to a selected area or skin of the subject.

(i) about 0.1% to about 10% (w/w) estradiol;

(ii) about 0.1% to about 5% (w/w) thickener;

(iii) an alcohol; and

(iv) water.

Claim 2 (canceled).

Claim 3 (previously presented): The method of claim 1, wherein the methyltestosterone is administered in the form of a tablet, capsule, cachet, lozenge, dispensable powder, granule, solution, suspension, emulsion or liquid.

Claims 4-8 (canceled).

Claim 9 (currently amended): The method of claim 1 8, wherein the ~~estradiol~~ second pharmaceutical composition is ~~administered~~ in the form of a hydroalcoholic gel.

Claim 10 (currently amended): The method of claim 1 9, wherein the second pharmaceutical composition ~~hydroalcoholic gel~~ further comprises ~~at least one of a lower alcohol, a penetration enhancer, and a thickener.~~

Claim 11 (original): The method of claim 1 θ , wherein the ~~lower~~ alcohol is selected from the group consisting of ethanol, 2-propanol, and mixtures thereof.

Claim 12 (canceled).

Claim 13 (currently amended): The method of claim 1 θ , wherein the thickener is polyacrylic acid.

Claims 14-19 (canceled).

Claim 20 (previously presented): The method of claim 1, wherein the methyltestosterone and the estradiol are each provided as a separate component of a kit.

Claim 21 (canceled).

Claim 22 (previously presented): The method of claim 1, wherein the methyltestosterone and the estradiol are administered in a sequential manner.

Claim 23 (previously presented): The method of claim 1, wherein the methyltestosterone and the estradiol are administered in a substantially simultaneous manner.

Claims 24-73 (canceled).

Claim 74 (new): The method of claim 1, wherein the second pharmaceutical composition comprises 0.06% (w/w) estradiol.

Claim 75 (new): The method of claim 1, wherein the second pharmaceutical composition comprises 0.03% (w/w) estradiol.

Claim 76 (new): A method for the treatment, prophylaxis, or reduction of the risk of developing a menopause disorder in a human female mammalian subject in need thereof, comprising a combination therapy of:

(a) orally administering a pharmaceutical composition comprising about 0.2 mg to about 50.0 mg of methyltestosterone; and

(b) percutaneously administering to a selected area of skin, about 5 g to about 10 g per day of a pharmaceutical composition comprising:

- (i) about 0.06% to about 10.0% estradiol
- (ii) about 0.1% to about 5.0% polyacrylic acid;
- (iii) about 0.1% to about 5.0% triethanolamine;
- (iv) about 30.0% to about 98.0% ethanol; and
- (v) water in an amount sufficient to make the formulation 100%,

wherein the percentages of components are weight to weight of the formulation.